

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)	
FENFLURAMINE/DEXFENFLURAMINE))	MDL NO. 1203 -
PRODUCTS LIABILITY LITIGATION)	
)	
THIS DOCUMENT RELATES TO:)	
)	
SHEILA BROWN, et al.)	CIVIL ACTION NO. 99-20593
v.)	
AMERICAN HOME PRODUCTS)	2:16 MD 1203
CORPORATION)	

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8437

Bartle, C.J.

March 18, 2010

Janice Wright ("Ms. Wright" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In April, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Allen L. Dollar, M.D., F.A.C.C. Based on an echocardiogram dated March 1, 2002, Dr. Dollar attested in Part II of Ms. Wright's Green Form that she suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 50%

2. (...continued)

describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

to 60%.³ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$449,381.⁴

In the report of claimant's echocardiogram, Dr. Dollar estimated claimant's ejection fraction to be 60%. An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See Settlement Agreement § IV.B.2.c.(2)(b)iv).

In November, 2002, the Trust notified Ms. Wright that her claim was selected for audit.⁵ Despite an opportunity to do

3. Dr. Dollar also attested that claimant suffered from moderate aortic regurgitation. As Ms. Wright's claim does not present any of the complicating factors necessary to receive Matrix Benefits for damage to her aortic valve, her level of aortic regurgitation is not relevant to this claim. See Settlement Agreement § IV.B.2.c.(2)(a).

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician's finding of moderate mitral regurgitation, the only issue is whether claimant has a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim.

5. Under the Settlement Agreement, Wyeth and the Trust each designated for audit a certain number of claims for Matrix Benefits and identified the condition(s) to be reviewed during the audit. See Settlement Agreement §§ VI.E. & VI.F.; Pretrial Order ("PTO") No. 2457 (May 31, 2002), Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures") § III.B. Here, the auditing cardiologist was asked to review claimant's level of mitral regurgitation, level of aortic regurgitation, and ejection fraction. In PTO No. 2662 (Nov. 26, 2002), we ordered the Trust to audit every claim submitted for Matrix Benefits. The present claim was designated for audit prior to the court's issuance of

(continued...)

so, claimant did not submit additional medical information in support of her claim. In January, 2003, the Trust forwarded the claim for review by Donna R. Zwas, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Zwas concluded that there was no reasonable medical basis for Dr. Dollar's finding that claimant had a reduced ejection fraction. Dr. Zwas explained that claimant's ejection fraction was greater than 60%.

Based on the auditing cardiologist's finding that claimant did not have a reduced ejection fraction, the Trust issued a post-audit determination denying Ms. Wright's claim. Pursuant to the Audit Policies and Procedures, claimant contested this adverse determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2457, Audit Policies and Procedures § IV.C.⁶ The Trust then applied to the court for issuance of an Order to show cause why Ms. Wright's claim should be paid. On July 31, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2950 (July 31, 2003).

5. (...continued)
PTO No. 2662.

6. Claims placed into audit on or before December 1, 2002 are governed by the Audit Policies and Procedures, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Rules for the Audit of Matrix Compensation Claims, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Policies and Procedures contained in PTO No. 2457 apply to Ms. Wright's claim.

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on October 7, 2003, and claimant submitted a sur-reply on October 21, 2003. Under the Audit Policies and Procedures, it is within the Special Master's discretion to appoint a Technical Advisor⁷ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Policies and Procedures § VI.J. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. § VI.O.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had a reduced ejection fraction. See id. § VI.D. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue,

7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. § VI.Q. If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id.

In support of her claim, Ms. Wright submitted an affidavit and echocardiogram report from Dr. Dollar wherein he reiterated his finding of a reduced ejection fraction. Claimant also submitted an affidavit and supplemental report of claimant's echocardiogram from David R. Clarke, M.D.⁸ Dr. Clarke agreed with Dr. Dollar's finding of a reduced ejection fraction and determined that claimant's ejection fraction was 50%. Claimant also argues that the determination by Dr. Zwas that claimant had a normal ejection fraction was based "solely on a visual assessment."

In response, the Trust forwarded claimant's echocardiogram tape to Dr. Zwas for a second review. Dr. Zwas submitted a declaration in which she reaffirmed her earlier determination that there was no reasonable medical basis for the attesting physician's finding of a reduced ejection fraction. Specifically, Dr. Zwas stated that "[a]lthough the echocardiogram showed planimetry [sic] for the ejection fraction, the planimetry [sic] was poorly executed and extremely inaccurate.

8. Dr. Clarke is no stranger to this litigation. According to the Trust, he has signed in excess of 100 Green Forms on behalf of claimants seeking Matrix Benefits.

I concluded that the ejection fraction is clearly greater than 60%." In addition, the Trust argues that the Settlement Agreement does not require exact measurements of the ejection fraction. Finally, the Trust notes that Dr. Dollar made no measurements of claimant's ejection fraction, and he was unwilling to state that claimant's ejection fraction was below 60%.⁹

In her sur-reply, claimant argues that Dr. Dollar's conclusion that claimant's ejection fraction was 60% is sufficient to entitle Ms. Wright to Level II benefits. In addition, Ms. Wright submits that the Trust inappropriately raised a new argument by relying on the determination by Dr. Zwas that the planimetry for the ejection fraction was poorly executed and extremely inaccurate.¹⁰

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding

9. The Trust also argues that under Rule 26(a)(2) of the Federal Rules of Civil Procedure, physicians who proffer opinions regarding claims must disclose their compensation for reviewing claims and provide a list of cases in which they have served as experts. We disagree. We previously stated that Rule 26(a)(2) disclosures are not required under the Audit Policies and Procedures. See PTO No. 6997 at 11-12 n.13 (Feb. 26, 2007).

10. We disagree. The Audit Policies and Procedures permit the Trust to refute any arguments or explanations raised in claimant's response through the use of a verified expert opinion. See Audit Policies and Procedures § V.H. As the declaration by Dr. Zwas was in reply to claimant's response, we find that it is permitted under the Audit Policies and Procedures.

that Ms. Wright had a reduced ejection fraction. Specifically, Dr. Abramson found that:

In reviewing the transthoracic echocardiogram, my visual estimate is that the ejection fraction is >60%. I measured two ejection fractions at meter # 10:47:25 and 12:17:13 and calculated the ejection fractions to be 64% and 65% using the Simpson's Method of Disks. The technologist incorrectly traced a systolic volume at meter # 6:16 as a diastolic volume (the mitral valve is closed) obtaining an erroneously low ejection fraction.

In response to the Technical Advisor Report, claimant repeats the arguments she previously raised. In addition, she notes that "four different doctors reviewed the same tape and each one came up with a different value for the ejection fraction." Claimant also argues that the Technical Advisor did not explain why the attesting physician's finding of 60% was unreasonable.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, we disagree with claimant that Dr. Abramson did not explain why she found that there was no reasonable medical basis for the attesting physician's finding of a reduced ejection fraction. Dr. Abramson specifically stated that "[t]he technologist incorrectly traced a systolic volume at meter # 6:16 as a diastolic volume (the mitral valve is closed) obtaining an erroneously low ejection fraction." Claimant, moreover, does not challenge Dr. Abramson's determination that technical errors were made in connection with the attesting physician's finding of a reduced ejection fraction.

Finally, other than referencing the findings of her own cardiologists, claimant does not dispute Dr. Abramson's finding that her ejection fraction was "64-65%." In this instance, the attesting physician's representation cannot have a reasonable medical basis where the Technical Advisor concluded that claimant's ejection fraction was incorrectly calculated and greater than the required threshold. Thus, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

We also disagree with claimant's challenge to the auditing cardiologist's visual estimation of claimant's ejection fraction. Although the Settlement Agreement specifies the percentage needed to qualify as having a reduced ejection fraction for purposes of a mitral valve claim, it does not specify that actual measurements must be made on an echocardiogram.¹¹ As we explained in PTO No. 2640, "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." See PTO No. 2640 at 15 (Nov. 14, 2002). Similarly, eyeballing an ejection fraction to assess severity is an accepted echocardiographic practice. Claimant essentially requests that we write into the Settlement Agreement a requirement that actual measurements of a claimant's ejection fraction be made to determine if a claimant qualifies

11. Significantly, despite making this argument, claimant ignores that her own attesting physician did not provide measurements to support his finding of a reduced ejection fraction, but rather "estimated" her ejection fraction as 60%.

for Matrix Benefits. There is no basis for such a revision and claimant's argument is contrary to the "eyeballing" standards we previously have evaluated and accepted in PTO No. 2640.¹²

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had a reduced ejection fraction. Therefore, we will affirm the Trust's denial of Ms. Wright's claim for Matrix Benefits.

12. Claimant's argument also is flawed because the Technical Advisor, although not required to, made specific measurements of claimant's ejection fraction, which further establishes that claimant is not entitled to Matrix Benefits.